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The Outpatient Cost of Diabetes Care in Italian Diabetes Centers

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ABSTRACT

Objective: To provide resource utilization patterns and cost estimates of outpatient care for types I and II diabetes mellitus in Italy, based on retrospectively collected data.
Design: Multicenter, retrospective observational study analyzing individual costs in a sample of patients with diabetes mellitus.
Study population: A total of 2260 patients were stratified into eight groups by type of diabetes, glycemic control, and age.
Setting: Thirty-five centers for diabetes care in Italy.
Results: The per-patient cost of treatment was €136.8 in two months for type I diabetes ($N = 592$) and €123.3 for type II diabetes ($N = 1668$). Pharmaceutical therapy consisting of antidiabetic drugs only accounted for only 32% to 36% of treatments cost in type I patients and between 13% and 24% in type II. Diagnostic tests accounted for 27% to 42% of treatment costs in patients with both type I and type II diabetes, day-hospital days accounted for 15% to 22% in type I, 25% to 27% in type II, and consultations accounted for 16% to 20% in type I patients and between 17% and 21% in type II diabetes.
Conclusion: Despite limitations caused by the short period considered, and considering that in Italy the cost of diabetes has received limited attention, we believe this study presents some interesting information on the burden of diabetes in this country.
Keywords: diabetes, resource utilization, Italy, direct costs, health care.

Introduction

Diabetes mellitus is one of the most common chronic pathologies challenging doctors today. It is among the major causes of death in most developed countries [1]. The main associated complications—cardiovascular disease, nephropathy, retinopathy, and neuropathy—lead to disability, reduced life expectancy, and huge health care costs [2]. The economic burden of diabetes and its complications are considerable in health care and loss of productivity. Increasing awareness of the economic burden has led to many studies that address economic questions [3–13].

Etiological, clinical, and epidemiological differences distinguish types I and II diabetes. In turn, the characteristics of both types of diabetes often differ from those associated with impaired glucose tolerance. As a result, the socioeconomic impact of diabetes is likely to differ in patients with types I and II diabetes and impaired glucose tolerance [14].

This article provides resource utilization patterns and cost estimates of outpatient care for types I and II diabetes mellitus in Italy, based on the retrospectively collected data of the RECORD (Rilevazione Economica dei COsti e Risorse nel Diabete) project, a vast study including diabetes centers that are examining the economic burden of diabetes in Italy. RECORD was conducted by CESAV, the Mario Negri Institute Centre for Health Economics, under the auspices of three Italian medical societies specializing in diabetes (AMD: Associazione Medici Diabetologici; SID: Società Italiana Diabetologia; SIEDP: Società Italiana di Endocrinologia e Diabetologia Pediatrica). This article is focused on the cost of treating diabetic patients in diabetes centers, a selected subgroup of the entire diabetic patient population. According to significant estimates [15], in Italy 50% of diabetics are followed in diabetes centers. These patients are similar in terms of type of diabetes, age, and therapy to those cared for in general practice. However, the health care provided in diabetes centers may

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be rather different than in general practice. In fact, although it is reasonable to assume the absence of relevant differences in traditional aspects of clinical practice such as cardiovascular risk factor control and dietetic counseling, a greater diffusion of the procedures more strictly related to diabetes is likely in diabetes centers.

Methods

The RECORD project is a multicenter, observational study in which 35 diabetes centers located in 12 different regions of Italy participated: 16 from the north, 10 from the center, and 9 from the south. Diabetes centers participated in the project on a voluntary basis. Patients eligible for the study had a confirmed diagnosis of type I or II diabetes, had been attending the center for at least two years, and had been observed there for a follow-up consultation during a two-month enrollment period (between May and September 1998). Pregnant women were excluded.

Each diabetes center selected between 60 and 100 patients. Eligible patients were enrolled either consecutively starting from the first day of the enrollment period, or randomly according to a computer-generated list. Most centers (28 out of 35) followed the first method. Information regarding rate of participation was not collected centrally, but an informal inquiry estimated eligible patients who refused to enter the study at a negligible 2.1%.

A total of 2260 patients entered the study. For the purpose of analysis they were classified into eight prognostic groups by type of diabetes (type I or type II), age (age $\leq$60 or $>$60), and metabolic control (HbA1c $<$ or $>$7.5%), as follows:

Group 1: Type I, age $\leq$60, HbA1c $<$ 7.5%;
Group 2: Type I, age $\leq$60, HbA1c $>$ 7.5%;
Group 3: Type I, age $>$60, HbA1c $<$ 7.5%;
Group 4: Type I, age $>$60, HbA1c $>$ 7.5%;
Group 5: Type II, age $\leq$60, HbA1c $<$ 7.5%;
Group 6: Type II, age $\leq$60, HbA1c $>$ 7.5%;
Group 7: Type II, age $>$60, HbA1c $<$ 7.5%; and
Group 8: Type II, age $>$60, HbA1c $>$ 7.5%.

Metabolic control was evaluated on the basis of the glycosylated hemoglobin values dating back no more than 3 months before the interview. Most of the centers used high-performance liquid chromatography [16] to determine glycosylated hemoglobin, normal values ranging from 3.4% to 6.5%.

Data on resource consumption were collected retrospectively for the 2 months preceding enrollment using a standardized questionnaire completed by physicians in the participating centers. Personal information about each patient and data about complications, day-hospital admissions, drug therapy (oral antidiabetic drugs and insulin only) consultations, laboratory tests, and diagnostic procedures were collected.

Cost Estimates

The direct costs of diabetes outpatient care were estimated from the Italian National Health Service (INHS) perspective. Costs related to hospital admissions and lost production were not included.

The INHS provides universal coverage and comprehensive health care free at the point of delivery. Inpatient and outpatient specialist care is now funded according to a prospective per-case payment system based on region-wide fee schedules, a system like that of the Diagnosis Related Group (DRG) introduced in Italy in 1995.

With respect to unit costs, specialist consultations, diagnostic tests, and day-hospital days were evaluated according to INHS tariffs. Drug costs were calculated by multiplying the daily dose by the consumer price [17].

Data Analysis

The mean number of day-hospital days, outpatient consultations, diagnostic tests, and hours of pharmaceutical therapy were calculated for each prognostic group. Total costs of diagnosis and treatment were calculated by multiplying each resource consumed (consultations, diagnostic tests, admissions, and drugs) by its unit cost as identified above. Per-patient total costs were calculated by dividing total costs by the total number of patients.

Confidence intervals were calculated for total costs and subtotals (i.e., day-hospital days, consultations, diagnostic tests, and drugs). Poisson distribution was used for day-hospital and consultation subtotals since these variables were not normally distributed. Analysis of variance was used to test differences between groups ($P < .05$).

Covariance analysis was done for total costs to test the potential effect of the covariates not used for grouping patients: sex and number of complications per patient (grouped as 0, 1, 2, $\geq$3).

Results

The general characteristics of the study population are shown in Table 1. The distribution by sex was fairly balanced in all the prognostic groups. As expected, the mean age was significantly higher for patients with type II diabetes. The most frequent

Table 1 Patient population

	Type I diabetes								Type II diabetes							
Age	⩽60 years				>60 years				⩽60 years				>60 years			
HbA1c	<7.5%		>7.5%		<7.5%		>7.5%		<7.5%		>7.5%		<7.5%		>7.5%	
Number of patients	246		236		49		61		337		273		557		501	
	mean	range	mean	range	mean	range	mean	range	mean	range	mean	range	mean	range	mean	range
Age (years)	35.2	14–60	37.4	14–60	66.8	61–78	68.3	61–86	52.8	28–60	53.0	26–60	70.0	61–94	70.2	61–93
Age at clinical onset	23.1	2–56	22.1	2–55	37.5	11–68	39.3	11–68	46.1	28–60	43.7	20–69	58.4	25–83	55.5	21–82
Sex	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
Male	132	53.7	102	43.2	24	49.0	24	39.3	203	60.2	127	46.5	308	55.3	218	43.5
Female	114	46.3	134	56.8	25	51.0	37	60.7	134	39.8	146	53.5	249	44.7	283	56.5
Complications*																
Simple retinopathy	33	13.4	56	23.7	8	16.3	24	39.3	31	9.2	47	17.2	111	19.9	105	21.0
Proliferative retinopathy	28	11.4	39	16.5	17	34.7	19	31.2	34	10.1	28	10.3	55	9.9	75	15.0
Blindness	2	0.8	1	0.4	0	0.0	0	0.0	2	0.6	1	0.4	0	0.0	2	0.4
Neuropathy	25	10.1	60	25.4	25	50.0	36	59.0	35	10.4	50	18.3	101	18.1	139	27.8
Erectile dysfunction†	6	0.05	12	0.1	4	0.2	8	0.3	16	0.1	18	0.1	46	0.1	49	0.2
Nephropathy	30	12.2	29	12.3	8	16.3	15	24.6	33	9.8	21	7.6	55	9.9	82	16.4
Renal failure	3	1.2	3	1.3	4	8.2	1	1.6	3	0.9	2	0.7	19	3.4	16	3.2
Arterial hypertension	22	8.9	32	13.6	23	46.9	27	44.3	133	39.5	124	45.6	326	58.5	278	55.5
Hyperlipidemia	18	7.3	20	8.5	8	16.3	17	27.9	94	27.9	85	31.0	150	26.9	163	32.5
Cardiopathy	4	1.6	4	1.7	5	10.2	19	31.1	51	15.2	41	14.9	178	32.0	152	30.4
Claudication	3	1.2	2	0.9	2	4.1	5	8.2	9	2.7	10	3.7	35	6.3	34	6.8
Diabetic foot	6	2.4	13	5.5	2	4.1	10	16.4	10	3.0	9	3.3	46	8.3	43	8.6

*Chi square test was used to verify the significance ($p < .05$) of differences among groups.
†Calculated only on males.

complications in patients with type I diabetes were retinopathy, neuropathy, and arterial hypertension, and the percentage of affected patients was significantly higher in the older groups. In patients with type II diabetes the most frequent complications were retinopathy, arterial hypertension, and hyperlipidemia.

Table 2 shows the resources consumed by patients for diabetes treatment. In general, patients with type I diabetes had a higher mean number of consultations than those with type II. Type II patients had more diagnostic tests and day-hospital days than type I patients, but these differences were not statistically significant.

Table 3 shows the cost estimates, i.e., resources consumed multiplied by their unit costs. These estimates are also presented separately by type of diabetes (Type I or II), age, and blood glucose control. The per-patient cost of treatment was €136.8 in the two months for type I diabetes ($N = 592$) and €123.3 for type II diabetes ($N = 1668$). There were differences between the eight prognostic groups, but the treatment cost was higher only for group 4 (€148.8), i.e., patients with type I diabetes aged over 60 years and with HbA1c > 7.5%. However, this difference was also not statistically significant.

Covariance analysis was also used to take into account the effect of sex and number of complications on total costs. The adjusted means of total costs per patient were, respectively, €160.2 (STD 13.6), €157.5 (STD 13.6), €107.0 (STD 30.0), €126.5 (STD 26.9), €131.5 (STD 11.4), €126.9 (STD 12.6), €115.8 (STD 8.9), €121.1 (STD 9.4). Differences between groups were again not significant.

Pharmaceutical therapy accounted for 32% to 36% of the treatment cost in type I patients and 13% to 24% in type II. In type I diabetes the highest drug cost was for insulin (96–99%) while for type II it represented only 36% to 57%. Diagnostic tests accounted for 27% to 42% of the treatment cost in types I and II diabetes, day-hospital days for 15% to 22% in type I patients, 25% to 27% for type II, consultations for 16% to 20% in type I and 17% to 21% in type II diabetes.

Discussion

Potential limits of the study must be borne in mind. First of all, only patients, not centers, were randomly selected and the study population consisted of patients referred to a network of specialized centers. They cannot be considered representative

Table 2 Management of diabetes in an ambulatory setting (mean number per two months per 100 patients)

	Type I diabetes				Type II diabetes			
Age	⩽60 years		>60 years		⩽60 years		>60 years	
HbA1c	<7.5%	>7.5%	<7.5%	>7.5%	<7.5%	>7.5%	<7.5%	>7.5%
Number of patients	246	236	49	61	337	273	557	501
Consultations	173.3	194.8	196.2	224.6	189.0	184.8	150.4	177.4
Diabetologic consultations	72.8	86.0	75.6	93.4	70.0	77.4	53.0	68.6
Other specialist consultations	27.6	22.8	45.0	37.8	49.0	30.0	44.4	40.2
Diagnostic tests	581.6	560.2	581.4	637.6	611.8	594.8	585.9	640.4
Glycemia	186.6	200.4	171.4	241.0	186.4	214.2	177.4	211.6
Hba1c	130.0	102.6	104.0	109.8	101.2	94.8	88.6	110.8
Fructosamine	15.0	15.2	18.4	9.8	12.4	11.4	11.6	10.0
Lipidemic profile	21.2	24.6	47.0	32.8	38.2	38.6	35.6	36.2
Microalbuminuria	48.8	43.2	42.8	39.4	38.0	37.6	36.2	42.8
Urine test	53.2	48.8	53.0	57.4	62.8	55.8	51.6	58.8
Urine culture	10.6	5.6	10.2	8.2	16.6	8.4	16.0	12.8
Serum creatinine	28.0	30.0	47.0	46.0	36.8	38.0	36.8	40.6
ECG	14.2	17.0	24.4	24.6	24.6	21.6	32.0	27.0
Autosomic test	7.8	4.2	2.0	1.6	7.4	5.2	9.8	9.0
EMG	2.8	1.2	2.0	3.2	1.4	3.2	2.8	1.6
Neurologic visit	9.8	8.4	18.4	3.2	13.6	13.2	13.6	13.8
Cultures	1.2	1.2	—	1.6	5.0	2.6	3.2	3.2
Lower limb rx	0.4	2.2	—	—	4.4	0.8	4.8	3.6
Arteriography	—	—	—	—	0.6	—	0.2	0.4
Lower limb Doppler test	3.6	6.4	—	6.6	19.4	11.6	18.6	15.8
Ulcer medication	4.4	10.2	—	19.6	0.6	0.4	11.1	4.8
Fundus oculi examination	32.6	31.4	36.8	28.0	32.6	33.6	29.0	31.2
Fundus photography	4.4	1.6	—	3.2	5.0	1.2	2.2	3.0
Fluoroangiography	7.0	6.0	4.0	1.6	4.8	2.6	4.8	3.4
Day-hospital days	10.2	13.2	8.2	14.8	14.0	13.6	14.4	14.4

Table 3 Per-patient average cost/two months of observation (euros)

	Type I diabetes				Type II diabetes			
Age	⩽60 years		>60 years		⩽60 years		>60 years	
HbA1c	<7.5%	>7.5%	<7.5%	>7.5%	<7.5%	>7.5%	<7.5%	>7.5%
Number of patients	246	236	49	61	337	273	557	501
Total cost (euros)	131.2	140.9	126.3	148.8	119.6	122.2	121.5	130.0
CI	(112.4–150.7)	(125.5–158.1)	(96.4–156.4)	(113.8–188.3)	(102.3–143.6)	(107.9–139.7)	(100.3–149.4)	(117.4–155.1)
Consultations	20.7	22.5	24.9	27.1	24.6	22.2	20.1	22.5
CI*	(20.1–21.3)	(21.9–23.1)	(23.5–26.3)	(25.8–28.4)	(24.1–25.1)	(21.6–22.7)	(19.7–20.5)	(22.1–22.9)
Diabetologic consultations	15.0	17.8	15.6	19.3	14.5	16.0	10.9	14.2
Other specialist consultations	5.7	4.7	9.3	7.8	10.1	6.2	9.2	8.3
Outpatient diagnostic tests	42.0	38.6	40.5	40.7	47.8	40.1	50.7	45.6
CI	(30.3–54.2)	(31.7–47.3)	(25.0–56.2)	(22.2–63.7)	(40.9–61.8)	(34.5–49.2)	(44.2–61.2)	(43.7–60.2)
Glycemia	2.4	2.6	2.2	3.1	2.4	2.8	2.3	2.7
Hba1c	13.8	10.9	11.0	11.6	10.7	10.0	9.4	11.7
Fructosamine	0.5	0.5	0.6	0.3	0.4	0.4	0.4	0.3
Lipidemic profile	0.4	0.5	0.9	0.6	0.7	0.7	0.7	0.7
Microalbuminuria	2.3	2.0	2.0	1.8	1.8	1.7	1.7	2.0
Urine test	1.1	1.0	1.1	1.2	1.3	1.2	1.1	1.2
Urine culture	0.9	0.5	0.8	0.7	1.4	0.7	1.3	1.1
Serum creatinine	0.3	0.4	0.6	0.6	0.5	0.5	0.5	0.5
ECG	6.6	7.9	11.3	11.4	11.4	10.0	14.9	12.5
Autosomic test	3.2	1.7	0.8	0.7	3.1	2.1	4.0	0.0
EMG	0.9	0.4	0.6	1.0	0.4	1.0	0.9	0.5
Neurologic visit	2.0	1.7	3.8	0.7	2.8	2.7	2.8	2.9
Cultures	0.2	0.2	—	0.3	0.8	0.4	0.5	0.5
Lower limb rx	0.1	0.4	—	—	0.8	0.1	0.9	0.6
Arteriography	—	—	—	—	1.7	—	0.6	1.1
Lower limb Doppler test	0.7	1.0	—	0.4	2.6	1.8	2.5	2.2
Ulcer medication	0.7	1.7	—	3.3	0.1	0.1	1.9	0.8
Fundus oculi examination	2.5	2.4	2.9	2.2	2.5	2.6	2.2	2.4
Fundus photography	0.2	0.1	—	0.1	0.2	0.0	0.1	0.1
Fluoroangiography	3.3	2.8	1.9	0.7	2.2	1.2	2.2	1.6
Drugs	45.6	50.3	42.5	47.9	15.9	29.4	18.3	29.6
CI	(43.1–48.4)	(48.0–52.8)	(36.7–48.7)	(43.4–52.5)	(14.1–17.7)	(26.7–32.3)	(16.7–19.9)	(27.8–31.6)
Biguanides	0.2	—	0.3	0.1	1.4	1.9	0.7	0.5
Sulfonamides	0.0	0.1	—	—	3.8	3.6	3.8	3.3
Biguanides & sulfonamides	—	0.2	—	0.9	3.6	7.5	3.9	6.4
Acarbosium	0.5	0.4	0.7	0.9	1.4	2.9	1.6	2.4
Insulin	44.9	49.6	41.5	46.0	5.7	13.5	8.3	17.0
Insulin/total	98%	99%	98%	96%	36%	46%	46%	57%
Day-hospital days	22.9	29.6	18.4	33.2	31.4	30.5	32.3	32.3
CI*	(22.3–23.5)	(28.9–30.3)	(17.2–19.6)	(31.8–34.6)	(30.8–32.0)	(29.8–31.2)	(31.8–32.8)	(31.8–32.8)

*CI calculated using Poisson distribution.

of the Italian diabetic population. However, Italian centers for diabetes care treat more than half of the estimated total of Italian diabetics. A study conducted in northern Italy showed that the two groups of diabetic patients, those attending and those not attending diabetes centers, were similar in terms of class, age, and type of therapy [15]. Also, the 35 centers participating in this study were well distributed across the main regions of the country.

Another limit of the study is that resource use data was retrospectively collected over only two months of observation. Although the sample of patients was large, this short time horizon might not be enough to extrapolate data on a yearly basis. This study did not consider the costs of hospitalization, which account for 30% to 50% of all diabetes-related costs [18]. This choice was made because: 1) the low expected rate of hospital admissions in the short period of retrospective analysis was likely to be subject to marked random fluctuation; and 2) collecting precise information on hospital admissions from the Italian diabetes centers was difficult because they lack inpatient wards.

Finally, the study did not include indirect costs; it estimated only direct medical costs from a payer perspective. Also, unit costs were based on INHS tariffs rather than on accurate estimates of real costs for each hospital.

The major strengths of this study include the possibility of analyzing resource consumption in a large body of diabetic patients using the same questionnaire for all centers and subjects. This should enhance the reliability of results across various age groups, individual characteristics and lifestyles, and severities of diabetes.

Most interesting, the analysis provides data separately for different clinical conditions. In this study the cost of diabetes treatment was similar in

patients with type II diabetes independent of patient age or metabolic control. The cost tended to be lower in patients with type I diabetes, except those over 60 years of age with poor metabolic control. Unfortunately, it is difficult to compare these results with published data, which generally refer to all diabetes patients, or to break them down to type I or type II only.

Among outpatient costs the proportion of cost for drugs accounted for 32% to 36% in type I diabetics, but 13% to 24% in type II, depending on age and metabolic control. Considering all patients, drugs accounted for about 27% of the total cost. Published figures on this issue are controversial. In some studies, drug costs are the major component of treatment of diabetes excluding hospitalization [19–21], but in others, drug costs were less than 20% [22–24]. Most of these differences reflect different methods of data collection, and particularly the types of costs included. Most of the studies do not indicate what drugs, types of laboratory tests, and consultations were considered. For example, comparing the results of this study with others [18], it should be remembered that only oral antidiabetic drugs and insulin costs were considered. Costs of the treatment of complications were excluded, and only the costs of diagnosing complications were included. This methodological choice stems from the difficulties, in the absence of a nondiabetic control group, of attributing to diabetes the cost of treating cardiovascular disease or other pathologies for which diabetes is a risk factor but not the only cause. This problem is particularly evident in older diabetic patients who have a high prevalence of comorbidity.

In conclusion, despite the limitations of the short period analyzed, and considering that in Italy the cost of diabetes has received limited attention, we believe this study offers some interesting information on the burden of diabetes in this country. In particular, this information can serve as a baseline for further economic evaluations of new therapies in diabetes care and may also be useful for health care decision makers who need to plan health care services with limited financial resources.

The analysis showed that the cost of diabetes, excluding complications, is not significantly affected by the diabetes type, metabolic control, or age.

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